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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,122	12/30/2003	Richard L. Boyd	NOR-014CP4 and 286336.153	3280

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EXAMINER	
MONTANARI, DAVID A	

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
06/24/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/749,122	BOYD, RICHARD L.	
	Examiner	Art Unit	
	DAVID MONTANARI	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-34,36-44,46-70,73-75 and 80-84* is/are pending in the application.

4a) Of the above claim(s) *27-34, 36-40, 42-44, 46-48, 50-70, 73-75, 80, 81, and 84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26,41,49,82,83 and 85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants arguments and amendments filed on 2/25/2008 have been entered.

2. Claim 26 has been amended.

3. Claim 85 is new.

4. The declaration by Dr. Richard Boyd has been considered.

5. The rejection of claims 26, 41, 49, 82 and 83 under 35 USC 112, 1st parag. lack of enablement is withdrawn in view of the evidence and arguments in the declaration by Dr. Richard Boyd.

6. Claims 26, 41, 49, 82, 83 and 85 are examined in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26, 41, 49, 82, 83 and 85 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating or increasing the resistance to a viral infection in a mammal comprising chemical castration to increase thymus production of T lymphocytes, does not reasonably provide enablement for a method of treating a viral infection in any patient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make and use the claimed invention, if not, whether an

artisan would have required undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue" (In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). Furthermore, USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of expertise.

The breadth of the claims encompass treating any species of animal with chemical castration, wherein the thymus of said animal does not degrade due to sex hormones.

At particular issue is the term "patient" in claim 26. This is problematic because given the broadest reasonable interpretation, this could include animals such as insects and fish which do have identifiable thymus-like organs which manufacture immune cells, but are not of the similarity to the thymus in mammals in the way that would fight viral infections as the thymus in mammals do (Nakashini et al., 2002, Developmental and Comparative Immunology, Vol. 26, pgs. 131-139). Further the art teaches that the involution of the thymus in fish is not tied to sexual maturity as in mammals (Deanesly et al., 1927, J. Cell Science, Vol. 281, pgs. 113-145). In view of these teachings in the art above the skilled artisan would question the effectiveness of

the claimed method in species of animals other than mammals. The changing of the claimed treatment method from a patient to a mammal would obviate this rejection.

Applicants working examples teach chemical castration of male mice and the resulting increase in thymic weight and T cell production. However the specification has failed to teach chemical castration in species of animals other than mammals. In view of the teachings in the art above, the skilled artisan would require an undue amount of experimentation without a predictable degree of success to make and use the invention as claimed. Thus limiting the claimed invention to a method of treating or increasing the resistance to a viral infection in a mammal comprising chemical castration to increase thymus production of T lymphocytes is proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26, 41, 49, 82, 83 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Windmill et al. (1998, Tissue and Cell. Vol. 30. pgs. 104-111) in view of Musey et al. (1997, N. England J. of Med., Vol. 337, pgs. 1267-1274) and Kendall et al. (1990, Cell Tissue Res., Vol. 261, pgs. 555-564).

Windmill et al. teach a method of castrating male SD rats to examine immunohistochemical data on post-castration changes in the thymus, spleen, and lymph nodes

(pg. 105, col. 1 parag. 2, 3 and 5). Windmill continues that the immediate effects following castration are increases in T cells, CD8 cells and B cells and that there is an increase in the ability of lymphocytes to respond to activation (pg. 105, Abstract). Windmill continues to teach that the thymus, particularly before puberty, plays an important role in immunological development but undergoes atrophy with age and that this atrophy is partially related to increased levels of sex hormones in the peripheral blood following puberty (pg. 104. col. 1 lines 3-10). Windmill continues that loss of specific cell types from the thymus with increasing age would obviously impinge upon immune function and that particularly there is a reduction in the T cell maturation process and an alteration in T cell numbers and function (pg. 104, col. 2 parag. 2). Windmill concludes that that castration in male SD rats results in increased thymic mass (pg. 106, Table 1), an enhanced immune response (pg. 111, col. 1 parag. 1 last 5 lines) and increases in thymic CD8 levels. Windmill does not teach a method of treating a viral infection using chemical castration or in an immunocompromised patient.

Musey et al. teach that in HIV-1 infected patients, cytotoxic T lymphocytes decrease in frequency over time (pg. 1267, col. 2 parag. 1 lines 4-7), that primary infection is typically associated with initially high levels of plasma HIV-1 RNA, and that HIV-1-specific cytotoxic T lymphocytes can appear early, with their emergence maybe coinciding with a decline in viral load (pg. 1267, col. 2 parag. 2 lines 1-6). Musey concludes that their findings indicate that virus-specific cytotoxic T lymphocytes may contribute to the control of early HIV-1 infection by reducing the viral load and slowing the progression of disease (pg. 1273, col. 1 parag. 3 lines 1-4). Musey does not teach a method of treating a viral infection in a patient using chemical castration to reactivate the thymus.

Kendall et al. teach that using chemical castration (Goserelin) significantly increased thymic weight and the re-appearance of a well defined cortex and medulla in the thymus of aged Wistar rats (pg. 555, Abstract). Kendall et al. does not teach a method of treating viral infection using chemical castration.

Thus the ordinary artisan would find it prima facie obvious to modify the method taught by Windmill et al. to treat immunocompromised patients infected with HIV-1 to increase thymus activity by increasing cytotoxic T lymphocyte output. Further the ordinary artisan would find that it is art recognized that HIV-1 infection in a patient results in an immunocompromised/immunosuppressed immune system. Windmill provides motivation to use castration in patient to bolster thymus activity by teaching that the thymus degrades post-puberty and that the inhibition of sex hormones via castration results in increased T lymphocyte production by the thymus. Musey provides additional motivation to the ordinary artisan to treat an immunocompromised patient, such as one afflicted with HIV-1, due to the importance of T lymphocyte cells to fight and maintain early HIV-1 infection. Additional motivation is added by Kendall et al. teaching that chemical castration significantly improves thymus weight and morphology. Thus the cited art provides the requisite teachings and motivation to make and use the invention as claimed.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID MONTANARI whose telephone number is (571)272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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